REMARKS:

The present Amendment revises the title, specification, drawings, claims and adds an Abstract to conform the present PCT application to the requirements of United States patent practice. The cancellation of claims 1-15 in favor of the claims presented herein has been made solely because the amount of strikethroughs and underlining that would have been necessary to confirm the original claims to the requirements of 35 U.S.C. §112, second paragraph would have been unduly burdensome and confusing. None of the differences in language between the claims presented herein and original claims 1-15 has been made for the purpose of distinguishing any of those claims over the teachings of any of the prior art of record. Accordingly, no Applicant does not consider any of the changes in language in the claims presented herein as constituted a surrender of any of the subject matter encompassed within the scope of original claims.

Early consideration of the PCT application on the merits is respectfully requested.

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~~Title~~

~~Implantable medical device~~

SPECIFICATION

TITLE

"IMPLANTABLE MEDICAL DEVICE OPERABLE IN A SPECIAL MODE UPON ACTIVATION DURING A PROGRAMMED TIME"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to an implantable medical device according to the preamble of the independent claim.

~~Background of the invention~~

Description of the Prior Art

It is known in the ~~art~~ field of implantable heart stimulators or pulse ~~generator~~ generators to use a magnet to change the pacemaker to a predetermined test mode, for indication of e.g. battery condition. Other predetermined modes may for instance be threshold tests or diagnostic data storage etc. When such a test is performed a magnetically strong test magnet is held at the skin of the patient in order to activate a detector. An activation of the detector results in a "magnet ON" detection, which in turn results in a change to the predetermined mode. Such a pacemaker is for instance disclosed in ~~US~~ United States Patent No. 4,390,020.

~~US~~ United States Patent No. 5,722,998 discloses an implantable medical device including a GMR sensor that inter alia is used to detect the presence of a magnetic field from a permanent magnet. When a magnetic field is detected ~~In that case~~ the sensor ~~is used to revert~~ causes the operation of the implantable device to revert to a magnet mode (also referred to as safe mode) of operation in

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which a predetermined, typically asynchronous, ventricular pacing rate is emitted ~~issued~~.

However, some medical interventions might interfere with the function of an implantable pulse generator such as a pacemaker. Examples are electrosurgery, diathermal treatment etc. In these cases one possibility is to program the IPG into a safe mode during the entire intervention. The device according to the '998 patent of course allows this, but at the cost of not allowing the device to be provided with a magnet test mode, since the magnet mode is reserved for the safe mode. The device according to the '020 patent does not allow a safe mode, but does allow the magnet test mode. To obtain a safe mode the device according to the '020 patent the device would have to be extensively reprogrammed by a cardiologist both before and after the medical intervention.

SUMMARY OF THE INVENTION

~~The problem to be solved by~~ An object of the present invention ~~thus~~ is to provide an IPG ~~which~~ that is more flexible in regard of the magnet mode than the prior art discussed above. It should be noted that, although the above prior art description is based on magnetic signal detectors, the advantages achieved by the invention ~~should also~~ encompass other signal detectors allowing a simple yes/no or on/off response to a signal.

The above object is achieved in an implantable medical device according to the invention having a mode control that operates components of the implantable medical device in a normal mode that includes a test mode, as well in at least one other mode that is outside of said normal mode. The implantable medical device has a signal detector that is responsive to an external activation and a timer that can be programmed with a specified time period. The signal detector and the timer are connected to the mode control, and if the external activation occurs during the time period, the mode control operates the components in the mode of operation that is outside of the normal mode, and if the signal detector detects the external activation outside of the time period, the mode control operates the components in the test mode within the normal mode.

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~~Summary of the invention~~

~~The above-mentioned object is achieved by the present invention as set forth in the independent claim.~~

~~Preferred embodiments are set forth in the dependent claims.~~

The present invention offers the opportunity to customize the ~~behaviour~~ behavior of an implantable medical device during a defined time period.

The new usage of applying the test magnet is that the magnet response is not the normal specified test ~~behaviour~~ behavior during a specific period. The function during magnet application will instead be what specifically has been ordered. The specific period has a limited length that is determined during a programming session. After that specific period has passed, the normal test ~~behaviour~~ behavior will occur ~~at~~ upon magnet application,

~~The feature~~ It is known in the prior art that a device, e.g. an implantable pacemaker, may have different programmed magnet responses, but the ~~response is not new. The new~~ feature ~~is~~ that after a predefined, limited tune period the specific ~~behaviour~~ behavior will end and the device will revert to the normal magnet response ~~behaviour~~ behavior is not known in the prior art.

~~Short description of the appended drawings~~

DESCRIPTION OF THE DRAWINGS

Figure 1 ~~shows~~ is a schematic block diagram of the present invention.

Figures 2-5 show time diagrams of three different scenarios that illustrate different aspects of the present invention.

~~Detailed description of preferred embodiments of the invention~~

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 ~~shows~~ is a schematic block diagram of the present invention including an implantable medical device 2 adapted to be operated in a normal mode of operation and in at least one other mode of operation and provided with a

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signal ~~detecting means~~ detector 4 responsive of an external activation 6 from an external activation means 8. The signal ~~detecting means~~ detector 4 is preferably a magnetic sensor responsive of an externally generated magnetic field. The magnetic sensor may be e.g. a reed element, a GNIR sensor or a Hall sensor.

The medical device is provided with a special ~~timing means~~ timer 10 adapted to be programmed with a specified time period (as indicated with the arrow 12). The programming is performed by an external programming unit 14 outside the body that communicates, e.g. via radio signals, with a communication ~~means~~ unit 16 in the medical device.

The medical device further includes a control ~~means~~ unit 18 responsive for the overall control of the function of the medical device. The different parts of the medical device are energized by a battery means (not shown).

According to a preferred embodiment of the present invention the medical device is an implantable heart stimulator, e.g. a pacemaker, a cardioverter or a defibrillator. In this case the medical device also includes a therapy means (not shown) adapted to generate a specific therapy.

The medical device is adapted to enter a predefined special mode of operation if an external activation is detected by the signal ~~detecting means~~ detector 4 during the specified time period, and the device is adapted to enter a normal test mode of operation if an external activation is detected by ~~said~~ the signal ~~detecting means~~ detector 4 outside the specified time period.

In the preferred embodiment where the medical device is a pacemaker a normal mode of operation may be a DDD mode, i.e. a dual chamber pacemaker provided with pacing and sensing capabilities in both heart chambers and having an inhibiting and triggering response to sensing.

If an external activation ~~means~~ element 8, preferably a magnet, is held at the skin 20 close to the medical device the mode of operation may be changed to a normal test mode.

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As indicated above the normal test mode may be for example for indication of the battery condition, for initiating a test of the stimulation threshold or to start ECG recordings or other diagnostic data storage.

The predefined special mode of operation is a safe operating mode where typically an asynchronous, ventricular pacing rate is issued. The parameters used to define the safe operating mode and the specified time period are preferably programmed and communicated to the communication means during one and the same programming session before a medical intervention.

The specified time period may in principle have any feasible value, but a practical upper limit may be a week and a lower limit may be in the order of a few hours, e.g. 1 hour.

Figures 2-5 show time diagrams of three different scenarios that illustrate different aspects of the present invention.

Each of the figures 2-5 shows, from above, the detection signal in the normal state (low) or in the detection state (high), and below follows horizontal bars representing the special time period, the normal mode of operation, the normal test mode of operation and the special mode of operation.

The signal ~~detecting means~~ detector 4 is adapted to generate a detection signal 22 (see figure 1) that is set in a detection state upon the detection of an external activation and remains in the detection state as long as the external activation persists. The detection signal is normally in a normal state.

The specified time period is normally much longer than the duration for the external activation.

In ~~figure~~ Figure 2 the present invention is illustrated.

In a typical situation where the present invention is applicable the patient is scheduled for e.g. a surgical operation involving some kind of procedure that could affect the ~~function~~ functioning of the patient's pacemaker. The patient first

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visits his or her cardiologist, e.g. the same day as the operation or some day before, ~~that~~ who determines ~~a~~ proper safe parameter settings, this being the special mode of operation, for the pacemaker during the surgical operation and also determines the special time period this setting should be used when an external activation is detected by the signal ~~detecting means~~ detector 4. The cardiologist then programs the pacemaker with the determined parameter settings and the special time period ~~by means of~~ using the external programming means.

The special time period preferably starts to run immediately after the special ~~timing means~~ timer 10 is programmed but could ~~also,~~ alternatively~~, starts~~ start to run a predetermined time after the programming is performed. This alternative situation could happen if the patient visits the cardiologist on a Friday and the planned surgical operation is during the next week (Monday to Friday).

The patient then ~~may~~ can undergo the planned surgical operation without the presence of the cardiologist. During the critical part(s) of the operation the surgeon/physician places a magnet on the skin outside the pacemaker that ~~enters~~ causes the pacemaker to enter the safe special mode of operation and ~~remains~~ to remain in that mode as long as the magnetic field is detected by the signal ~~detecting means~~ detector 4. This is seen in ~~figure~~ Figure 2 as the horizontal bar representing the special mode ~~which~~ that is activated when the detection signal is in its detection state.

When the magnet is taken away the pacemaker returns to the normal mode of operation. In ~~the figure~~ Figure 2 the duration of the detection signal in the detection state is, for illustrative purposes, much longer compared to the duration of the special time period than in most actual situations when the invention is used ~~in reality~~.

Figure 3 illustrates the ~~behaviour~~ behavior of the medical device if no special time period has been programmed, i.e. the normal test mode is activated when an external activation (the detection signal in a detection state) is applied.

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Figure 4 illustrates the unusual situation that occurs if the special time period runs out before the external activation is terminated. In that case the medical device remains in the special mode of operation entered during the specified time period even if the specified time period ~~runs~~ times out, as long as the detection signal is in the detection state.

Figure 5 illustrates a combination of the different scenarios shown in ~~figures~~ Figures 2-4 where a number of (three) activations are made, two within the duration of the special time period and one outside.

According to an alternative embodiment of the present invention the external activation are radio signals generated by the external activation means that may be included in the external programming unit. The radio signals being the external activation then includes a ~~signalling~~ signaling message in the form of e.g. radio pulses coded to be interpreted as activation, i.e. the detection signal is set in a detection state.

In this alternative embodiment the special mode of operation is ended by an external deactivation including a ~~signalling~~ signaling message in the form of e.g. radio pulses coded to mean deactivation.

According to another alternative embodiment the external activation has the form of light signals, either as continuous light or as activation and deactivation light pulses. The signal ~~detecting means~~ detector 4 is in this embodiment any suitable optical sensor.

~~The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.~~

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Although modifications and changes may be suggested by those skilled in the art, it is the invention of the inventor to embody within the patent warranted heron all changes and modifications as reasonably and properly come within the scope of his contribution to the art.